

Application No.: 10/698,676  
Amendment Dated: November 7, 2005  
Reply to Office Action of: July 5, 2005

In the Claims:

The current claim set of the application is presented below. Indications as to the status of the claims ("original," "currently amended," "canceled," "previously presented," "not entered," "new," etc.) appear in parentheses after the claim number. Deletions are identified in bold with double brackets and strikethrough (e.g. ~~[[deletion]]~~) and new text is identified in bold with underlining (e.g. **new language**).

1. (Currently amended) A method of delivering a denervating agent to a prostate gland, the method comprising:

inserting an imaging apparatus into a rectum of a patient, **wherein the imaging apparatus includes a hole at the distal tip;**

generating one or more images of the prostate gland via the imaging apparatus;

maneuvering a needle through the **hole at the distal tip of the** imaging apparatus and through a rectal wall of the patient;

positioning a distal end of the needle in proximity to the prostate gland based on the one or more images;

inserting the distal end of the needle into the prostate gland; and

delivering the denervating agent to the prostate gland via a lumen of the needle.

2. (Original) The method of claim 1, wherein inserting the distal end of the needle into the prostate gland comprises actuating a mechanism to cause the distal end of the needle to spring bias into the prostate gland.

3. (Original) The method of claim 1, wherein the imaging apparatus comprises an ultrasonic imaging device.

4. (Original) The method of claim 3, further comprising maneuvering the ultrasonic imaging device to generate the one or more images of the prostate gland.

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5. (Original) The method of claim 1, wherein the denervating agent includes botulinum toxin.
6. (Original) The method of claim 1, further comprising:  
inserting the needle into the prostate gland at a first location;  
delivering a first dose of the denervating agent to the prostate gland via the lumen of the needle;  
removing the distal end of the needle from the prostate gland at the first location;  
positioning the distal end of the needle in proximity to a second location of the prostate gland based on the one or more images;  
inserting the needle into the prostate gland at the second location; and  
delivering a second dose of the denervating agent to the prostate gland via the lumen of the needle.
7. (Original) The method of claim 6, further comprising:  
removing the distal end of the needle from the prostate gland at the second location;  
positioning the distal end of the needle in proximity to a third location of the prostate gland based on the one or more images;  
inserting the needle into the prostate gland at the third location; and  
delivering a third dose of the denervating agent to the prostate gland via the lumen of the needle.
8. (Original) The method of claim 7, further comprising:  
removing the distal end of the needle from the prostate gland at the third location;  
positioning the distal end of the needle in proximity to a fourth location of the prostate gland based on the one or more images;  
inserting the needle into the prostate gland at the fourth location; and  
delivering a fourth dose of the denervating agent to the prostate gland via the lumen of the needle.

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9. (Original) The method of claim 8, wherein each of the doses comprise approximately 0.5 milliliter of botulinum toxin.

10. (Original) The method of claim 1, further comprising delivering the denervating agent from a denervating agent delivery assembly that includes a reservoir to hold the denervating agent and an actuator to cause the denervating agent to flow from the reservoir through the lumen, wherein a hub and a fluid line attaches the needle to the reservoir.

11. (Original) The method of claim 1, further comprising delivering the denervating agent from a denervating agent delivery assembly that includes a first reservoir that holds a substantial amount of the denervating agent, a second reservoir to hold a first discrete dose of the denervating agent and an actuator to cause the denervating agent to flow from the second reservoir through the lumen, wherein a hub attaches the needle to the second reservoir and the second reservoir refills with a second discrete dose of the denervating agent from the first reservoir following delivery of the first discrete dose.

12. (Currently amended) A system for delivering a denervating agent to a prostate gland comprising:

an imaging apparatus sized for insertion into a rectum of a patient to generate one or more images of a prostate gland, the imaging apparatus formed with a hole;

a needle positioned through the hole of the imaging apparatus for insertion through a rectal wall of the patient in proximity to the prostate gland based on the one or more images, the needle defining a lumen such that a denervating agent can be delivered to the prostate gland through the lumen.

13. (Original) The system of claim 12, further comprising a spring mechanism to bias the needle into the prostate gland upon actuation.

14. (Original) The system of claim 13, further comprising an actuator to actuate the spring mechanism to bias the needle into the prostate gland.

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15. (Original) The system of claim 12, further comprising a denervating agent delivery assembly coupled to the needle to deliver the denervating agent through the lumen.
16. (Original) The system of claim 15, wherein the denervating agent delivery assembly includes a reservoir to hold the denervating agent and an actuator to cause the denervating agent to flow from the reservoir through the lumen.
17. (Original) The system of claim 16, wherein the second actuator comprises a plunger.
18. (Original) The system of claim 16, further comprising a hub and a fluid line to attach the needle to the reservoir.
19. (Original) The system of claim 15, wherein the denervating agent delivery assembly includes a first reservoir to hold a substantial amount of the denervating agent, a second reservoir to hold a discrete dose of the denervating agent, and an actuator to cause the denervating agent to flow from the second reservoir through the lumen, wherein the second reservoir refills with another discrete dose of the denervating agent from the first reservoir following actuation of the second actuator.
20. (Original) The system of claim 15, wherein the denervating agent delivery assembly includes an actuator, a pump and a reservoir, wherein upon actuation of the actuator the pump causes delivery of the denervating agent from the reservoir through the lumen.
21. (Original) The system of claim 12, wherein the denervating agent includes botulinum toxin.
22. (Original) The system of claim 12, wherein the imaging apparatus comprises an ultrasonic imaging apparatus.

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23. (Original) The system of claim 12, wherein the needle includes a hyper-echoic coating.

24. (Currently amended) A system for delivering a denervating agent to a prostate gland comprising:

an imaging means for insertion into a rectum of a patient to generate one or more images of a prostate gland, the imaging apparatus formed with a hole;

a needle means positioned through the hole of the imaging apparatus for insertion through a rectal wall of the patient in proximity to the prostate gland based on the one or more images, the needle defining a lumen such that a denervating agent can be delivered to the prostate gland through the lumen.

25. (Original) The system of claim 24, further comprising means for spring-biasing the needle into the prostate gland.

26. (Original) An ultrasonic imaging apparatus comprising:

a probe-shaped body defining a major longitudinal direction; and

a hole formed through the probe-shaped body along the major longitudinal direction, wherein the hole is sized to mate with a fluid delivery needle such that when the ultrasonic imaging apparatus images a location of a patient, the needle can be extended through the hole and out a distal end of the imaging apparatus to pierce the patient at the location.